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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,284	02/26/2004	Paul M. Skoneczny	GY0111 (NP)	5398
23914	7590	04/18/2008		
LOUIS J. WILLE BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			EXAMINER WALICKA, MALGORZATA A	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 04/18/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

10/787,284

**Applicant(s)**

SKONEZNY ET AL.

**Examiner**

MALGORZATA A. WALICKA

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-6, 8-9, 14-21, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6, 8-9, 14-21 and 25-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

The response filed Jan 18, 2008, comprising amendments to the claims and applicants' REMARKS regarding the Office Action mailed to applicants October 18, 2007, is acknowledged. Claims 1, 10-13 and 22-24 have been cancelled. Claims 2, 3, 5, 8, 9, 14-17, 19 and 20 have been amended. Pending claims 2-6, 8-9, 14-21 and 25-26 are pending and under examination.

## **DETAILED ACTION**

Rejections not repeated herein are withdrawn due to amendments or moot due to the cancellation of the claims.

### **Rejection under 35 USC 103**

Claims 2-6, 8-9, 14-18, 20 and 25-26 are rejected over Farina et al., US Patent 5,011,774 published Oct. 1991, in view of Daddona et al., published Oct. 1884 and common knowledge in the art as exemplified by Dessouki et al., published 2002. The reasons for rejection were explained in the last Office Action of My 9, 2007 and repeated in the Office Action of Oct. 18, 2007 (last action).

Claims 19 and 21 are rejected over Farina et al., US Patent 5,011,774 published Oct. 1991 (quoted in IDS), in view of Daddona et al., published Oct. 1884 (quoted in IDS) and common knowledge in the art as exemplified by Dessouki et al., published 2002 (quoted in IDS) and Beach et al (*Strategy for Industrial Scale Production of Dideoxyinosine: Enzymatic Deamination of Dideoxyadenosine by Adenosine*

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*Deaminase*, Nucleosides and Nucleotides, 1991, 10/7, 1499-1505, included in IDS).

The reasons for the rejection are the same as those explained in the last action.

Response to Applicants arguments

In the REMARKS, page 6 of 7 Applicants present their position as follows.

- 1) The Office has failed to provide a sound basis to combine the references in the manner suggested.
- 2) "Each test for prima facie obviousness applied by the Patent Office, e.g., the 'differences between the prior art and the claims' must be consistent with the legal principles enunciated in KSR."
- 3) " While the KSR Court rejected a rigid application of the teaching, suggestion, or motivation ('TSM') test in an obviousness inquiry, the Court acknowledged the importance of identifying 'a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination. KSR, t27 S",  
and further

"Thus, in cases involving new methods, it remains necessary to identify some reason that would have led a chemist to modify a known process in a particular manner to establish prima facie obviousness of a new claimed method."

Applicants' arguments have been fully considered but are found not persuasive for the following reasons.

Regarding point 1), it is not clear why the combination of the references in the manner suggested by the examiner in her rejection is lacking "sound basis", because in the rejection the examiner wrote

"It would have been obvious for one having skills in the art, who would like to produce the anti-HIV drug ddi, to use teachings of Farina et al. and replace calf enzyme of Farina by human adenosine deaminase taught by Daddona",  
page 5 line 11, and in the last paragraph of page 5,

"The motivation is provided by Farina et al: 'Although adenosine deaminase (ADA) from calf spleen was used in the actual examples, it is believed that any preparation of adenosine aminohydrolase (or 'deaminase,' EC 3.5.4.4.) would be suitable, column 6, line 8. Human adenine deaminase disclosed by applicants is a preparation of an adenosine aminohydrolase, or 'deaminase', and is classified as EC 3.5.4.4."

. Applicants furthermore, do not provide any specific reasons why the combination of the references in the examiner's manner is not "sound".

Regarding point 2) differences between the prior art and the claims are as they are and were clearly identified by the rejection. Applicants' do not provide any specific reasons why the analysis of these differences performed by the examiner is not consistent with the legal principles enunciated in KSR.

Regarding point 3), the 103 rejection presented in the previous actions is consistent even with a rigid application of the TSM test in the obviousness inquiry. The examiner clearly identifies in the body of the rejection the reasons that would have led a

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chemist to modify a known process in a particular manner. Applicants do not explain why, and which of, the reasons explained by the examiner are not sufficient or improper.

In summary, Applicants' argument being not persuasive are not sufficient to withdraw the rejection of claims 2-6, 8-9, 14-18, 19, 20, 21 and 25-26 under 35 USC section 103.

### **Conclusion**

All claims are rejected. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is

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(571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1652  
Patent Examiner

/Rebecca E. Prouty/  
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